



Medical Necessity Criteria for Topical Antifungals

Drug Class - Topical Antifungals

Background - After evaluating the relative clinical and cost effectiveness of the topical antifungals, the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, TMA.

Effective Date: 17 Aug 2005

- Ciclopirox (Loprox)
- Econazole (Spectazole)
- Oxiconazole (Oxistat)
- Sertaconazole (Ertaczo)
- Sulconazole (Exelderm)

Effective Date: 21 Feb 2007

- Miconazole 0.25% / zinc oxide 15% (Vusion)

Patients currently using a non-formulary topical antifungal may wish to consult their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.
3. Miconazole 0.25% / zinc oxide 15% (Vusion) is FDA-indicated for the adjunctive treatment of diaper dermatitis (diaper rash) only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast) in immunocompetent children 4 weeks of age and older. Other topical antifungals commonly used for diaper rash include higher concentrations of miconazole (2%), clotrimazole, and nystatin, often used in conjunction with zinc oxide ointment, an over-the-counter skin protectant.

Other Considerations:

- Some topical antifungals listed above are also available as over-the-counter products, which are not covered by TRICARE. Visit the Formulary Search Tool page to find if a specific product is over-the-counter.
- Brand-name topical antifungal products that have generic equivalents are not covered by TRICARE. Visit the Formulary Search Tool page to find if a specific product is over-the-counter.
- The non-formulary cost share applies to all products designated as non-formulary. Approval of medical necessity for such products reduces the cost share to the formulary.
- The following medical necessity criteria do not apply to Penlac Nail Lacquer (ciclopirox topical solution), which is available at the formulary cost share; however, prior authorization is required for Penlac.

Medical Necessity Criteria for Topical Antifungals

Ciclopirox (Loprox), oxiconazole (Oxistat), sertaconazole (Ertaczo), and sulconazole (Exelderm) - The \$22 non-formulary cost share may be reduced to the \$9 formulary cost share if the patient has tried ALL of the formulary alternatives or has a clinical reason(s) for not trying ALL of the alternatives, based on the following criteria:

1. The formulary agent is contraindicated (e.g., due to hypersensitivity).
2. The formulary agent is not available in the desired formulation.
3. The formulary agent caused or is likely to cause significant burning, itching, redness or other significant adverse effects.
4. An adequate treatment course with the formulary agent resulted in therapeutic failure.
5. The formulary agent is not effective for the treatment of the specific condition. For example, nystatin is not effective for the treatment of tinea pedis, corporis, cruris, or versicolor.

Miconazole 0.25% / zinc oxide 15% (Vusion) - The \$22 non-formulary cost share may be reduced to the \$9 formulary cost share if the patient has tried ALL of the formulary alternatives or has a clinical reason(s) for not trying ALL formulary alternatives, based on the following criteria. Formulary alternatives include higher concentrations of miconazole (2%), clotrimazole, and nystatin, which are often used in conjunction with zinc oxide ointment, an over-the-counter skin protectant.

1. The formulary agent is contraindicated (e.g., due to hypersensitivity).
2. The patient has experienced or is likely to experience significant adverse effects from the formulary agent.
3. The formulary agent is not available in the desired formulation.

Criteria approved through the DoD P&T Committee process May, 2005 and November, 2006

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TRICARE Pharmacy Program Medical Necessity Form for Topical Antifungals

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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- **Formulary topical antifungals** available at the formulary copay include butenafine (Mentax), clotrimazole, ketoconazole, miconazole, naftifine (Naftin), and nystatin. Topical formulations of **ciclopirox (Loprox)**, **econazole (Spectazole)**, **oxiconazole (Oxistat)**, **sertaconazole (Ertaczo)**, **sulconazole (Exelderm)**, and **miconazole 0.25% / zinc oxide 15% (Vusion)** are **non-formulary, but available to most beneficiaries at the non-formulary cost share**. The non-formulary designation applies to both the brand name and generic versions of these medications.
- You do **NOT** need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication *instead of a formulary medication* is medically necessary. If a non-formulary medication is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- TRICARE will not cover a non-formulary medication for Active duty service members unless it is determined to be medically necessary *instead of a formulary medication*. If a non-formulary medication is determined to be medically necessary, it will be available to Active duty service members at no cost share.

MAIL ORDER and RETAIL	<ul style="list-style-type: none">• The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477• The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com	MTF <ul style="list-style-type: none">• Non-formulary medications are available at MTFs only if both of the following are met:<ul style="list-style-type: none">○ The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.○ The non-formulary medication is determined to be medically necessary.• Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1 Please complete patient and physician information (Please Print)

Patient Name:	_____	Physician Name:	_____
Address:	_____	Address:	_____
Sponsor ID #	_____	Phone #:	_____
Date of Birth:	_____	Secure Fax #:	_____

Step 2 1. Please indicate which medication is being prescribed:

- | | |
|---|-------------------------|
| <input type="checkbox"/> ciclopirox (Loprox) | Please go to Question 2 |
| <input type="checkbox"/> econazole (Spectazole) | |
| <input type="checkbox"/> oxiconazole (Oxistat) | |
| <input type="checkbox"/> sertaconazole (Ertaczo) | |
| <input type="checkbox"/> sulconazole (Exelderm) | |
| <input type="checkbox"/> miconazole 0.25% / zinc oxide 15% (Vusion) | Please go to Question 3 |

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Ciclopirox (Loprox), econazole (Spectazole), oxiconazole (Oxistat), sertaconazole (Ertaczo), sulconazole (Exelderm)

2. Please indicate which of the reasons below (1-5) applies to each of the formulary alternatives listed in the table. You **MUST** circle a reason **AND** supply a specific written clinical explanation for **EACH** formulary alternative.

Formulary Alternative	Reason	Clinical Explanation
Butenafine (Mentax)	1 2 3 4 5	
Clotrimazole	1 2 3 4 5	
Ketoconazole	1 2 3 4 5	
Miconazole	1 2 3 4 5	
Naftifine (Naftin)	1 2 3 4 5	
Nystatin	1 2 3 4 5	

Acceptable clinical reasons for not using each of the formulary alternatives are:

1. The formulary agent is contraindicated (e.g., due to hypersensitivity).
2. The formulary agent is not available in the desired formulation.
3. The formulary agent caused significant burning, itching, redness or other significant adverse effects.
4. An adequate treatment course with the formulary agent resulted in therapeutic failure.
5. The formulary agent is not effective for the treatment of the specific condition. For example, nystatin is not effective for the treatment of tinea pedis, corporis, cruris, or versicolor.

Miconazole 0.25% / Zinc Oxide 15% Ointment (Vusion)

3. Please indicate which of the reasons below (1-2) applies to each of the formulary alternatives listed in the table. You **MUST** circle a reason **AND** supply a specific written clinical explanation for **EACH** formulary alternative.

Formulary Alternative	Reason	Clinical Explanation
Clotrimazole 1% (cream)	1 2 3	
Miconazole 2% (ointment or cream)	1 2	
Nystatin (ointment, powder, or cream)	1 2	

Note: Vusion is FDA-indicated for the adjunctive treatment of diaper dermatitis (diaper rash) only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast) in immunocompetent children 4 weeks of age and older. Other topical antifungals commonly used for diaper rash include higher concentrations of miconazole (2%), clotrimazole, and nystatin, often used in conjunction with zinc oxide ointment, a skin protectant.

Acceptable clinical reasons for not using each of the formulary alternatives are:

1. The formulary agent is contraindicated (e.g., due to hypersensitivity).
2. The patient has experienced or is likely to experience significant adverse effects from the formulary agent.
3. The formulary agent is not available in the desired formulation (clotrimazole only).

**Step
3**

I certify the above is correct and accurate to the best of my knowledge. By completing and signing this document you are confirming that the patient has either tried ALL of the formulary alternatives or has a clinical reason(s) for not trying ALL of the alternatives. Please sign and date:

Prescriber Signature

Date

Latest revision: September 28, 2011